IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

Alexandria Division

RUBY L. LOWE, *Power of Attorney for* MICHAEL A. TAYLOR, Plaintiff, v. CERNER HEALTH SERVICES, INC., Defendant.	)	Civil Action No. 1:19cv625

MEMORANDUM OPINION

THIS MATTER comes before the Court on the Plaintiff's and Defendant Cerner Health Services, Inc.'s ("Cerner HS") Motions for Summary Judgment. The undisputed evidence demonstrates that in 2006 Virginia Hospital Center ("VHC") purchased a highly configurable Electronic Health Records ("EHR") system called Soarian Clinicals. VHC understood that it was buying a "framework" that needed to be configured by VHC. Cerner HS provided the templates blank, so that VHC could create an ordering system tailored to its needs. These blank templates defaulted all orders for a start time of "now." For all orders that VHC chose to include in its system, teams of clinicians from VHC's pharmacy, nursing, and other departments determined the content they wanted available for clinicians entering those

orders. VHC also determined which orders it wanted to default to a start time other than "now." Soarian Clinicals was designed to allow VHC easily to populate those choices to suit its clinicians' regular practices and to change them at any time. VHC used Soarian Clinicals for six years without incident and without complaining to Cerner HS about any of the alleged "defects" Plaintiff raises in this lawsuit. VHC never notified Cerner HS about Mr. Taylor's injury that forms the basis of this lawsuit.

Mr. Taylor was injured in 2016 following gallbladder surgery at VHC. Mr. Taylor's surgeon incorrectly entered a pulse oximetry monitoring order into Soarian Clinicals and failed to review the order carefully (as she was required to do) before signing off. The nursing staff caring for Mr. Taylor similarly failed to follow VHC guidelines for patient monitoring and failed to question what the surgeon's pulse oximetry order meant. For these reasons, Plaintiff brought a medical malpractice suit against (and already settled with) VHC and the surgeon's and nurses' employers. Even then, VHC did not notify Cerner HS about Mr. Taylor's injury and made no complaint about Soarian Clinicals. Indeed, the majority of Soarian Clinicals' "defects" about which Plaintiff complains relate to configuration decisions and content choices *made by VHC* that were not present when VHC received the system. Plaintiff asserts two identical claims: one for negligent products liability and

another for negligence—both under theories of negligent design and failure to warn. Plaintiff cannot prevail because Soarian Clinicals did not contain a defect that rendered it unreasonably dangerous for foreseeable use. Further, the purported defect did not exist when the system left Cerner HS's control, and the purported defect was not the cause of Mr. Taylor's harm. Nor is Cerner HS responsible for any alleged failure to warn. No material issues of fact remain, and Cerner HS is entitled to judgment on each claim.

EHRs began as ordering systems for departments like the pharmacy as healthcare organizations moved away from paper ordering. As EHR systems matured, vendors began developing fully integrated technology platforms with data flowing between multiple departments. Today, EHR vendors offer a variety of solutions that come with differing levels of pre-loaded content and configurability.

Siemens, a former EHR vendor, created Soarian Clinicals in the early 2000s. Cerner HS acquired the assets of Siemens' health services business, including Soarian Clinicals, in February 2015. Soarian Clinicals includes computerized provider order entry ("CPOE") software, which clinicians use to enter orders electronically.

The U.S. government provides financial incentives to healthcare organizations if the EHR software they use is tested

and certified by the Office of the National Coordinator for Health Information Technology ("ONC"). ONC conducts certification testing on an EHR vendor's standard offerings prior to configuration and implementation by a healthcare system. "The ONC Health IT Certification Program provides assurance to any purchasers and other users that a system meets the technological capability, functionality, and security requirements" adopted by the Federal Government. Neither ONC nor any other recognized governing organization require usability testing of an EHR after it is configured and implemented by a healthcare system.

In order to attain ONC certification, an EHR vendor must conduct specific capability, functionality, and security testing on its CPOE software. ONC certification specifically requires "safety-enhanced design" testing, which requires the application of "user-centered design processes." User-centered design testing examines the software's effectiveness, efficiency, and satisfaction from the user's perspective. These ONC certification standards are the only government standards that apply to EHR vendors' systems, their usability, and their safety-enhanced design. The ONC certification standards are not mandatory on EHR vendors, but practically, vendors must meet these standards and gain certification because no rational healthcare organization would use an uncertified EHR and risk losing government reimbursement revenue.

Soarian Clinicals and its CPOE have been certified (including for having a safety-enhanced design) by the ONC since August 2014. In October 2014, ONC certified the specific version of the CPOE VHC used at the time of Mr. Taylor's care. Cerner HS also conducts internal testing of Soarian Clinicals' usability and safety throughout its entire development lifecycle: from product inception, through launch of the product into the market, and thereafter. Cerner HS follows Healthcare Information and Management Systems Society ("HIMSS") and other relevant guidelines in conducting its internal testing.

Soarian Clinicals is a highly configurable "toolkit" that allows clinicians and healthcare organizations to configure orders and other functions based on the way they practice medicine. In 2006, VHC chose to purchase Soarian Clinicals from Siemens after a bidding process that included several other vendors. VHC understood that it was purchasing a "framework" that must be "configured and built with [VHC's] workflows and [VHC's] permitted values." Siemens provided VHC blank order templates, the tools through which VHC could configure its own ordering system. The templates contained no content in the drop-down menus, and when delivered, the system defaulted all orders to a start time of "now."

Soarian Clinicals was designed to be easily configured by the customer (i.e., hospital or other healthcare organization).

Changes to the CPOE can be made through the adaptability tool, which Siemens trained each customer to use. The adaptability tool allows customers to add or remove drop-down menus with a few mouse clicks and change the default start time ("now") for any type of order by right-clicking the relevant menu and setting the desired start time in the "default" field. The adaptability tool also allows customers to program the system to issue a warning (in whatever form the customer chooses) when any given order type is chosen.

VHC used the adaptability tool to make changes to the CPOE with no assistance from Siemens or Cerner HS. When it installed the system in 2010, VHC made choices about which default start times it wanted to include. VHC leveraged information from its prior EHR system, Lastword, as a starting point to determine how to configure the CPOE based on VHC clinicians' prior practices.

Teams of VHC clinicians (from nursing, respiratory therapy, and pharmacy) reviewed the orders, frequencies, and default start times used in Lastword and decided what to adopt or to modify in Soarian Clinicals. VHC chose to include the recurrence "once" in the ordering system and defined that recurrence to default to a start time of 10:00 a.m. the next day. VHC testified that the 10:00 a.m. default start time was based on the recommendation of the pharmacy team.

After VHC chose its default start times for each recurrence,

it loaded them into the system. VHC was responsible for conducting (and did conduct) testing of the newly configured system. VHC also was primarily responsible for training its end users (i.e., clinicians) how to enter orders on the configured system. VHC developed—and primarily used—computer modules to train the system's end users. When entering an order, after information is selected in the ordering screen, the clinician must choose "Add to Order Session." That action moves the proposed order from the ordering screen to the unsigned orders list, which shows all orders yet to be signed by the clinician.

The unsigned orders list serves as the clinician's final review of the orders before she signs them. For any order with a future start time (in the present case, for pulse oximetry) the screen displays this future start time for the clinician. The clinician is responsible for reviewing each order, ensuring its accuracy, and then selecting "Sign [number] orders for [patient]." Selecting "sign" causes the orders to go into effect. The signature button displays the number of orders to be signed (and the scroll button is clearly visible) to alert the clinician that there may be orders to review below the first screen.

According to an audit trail, VHC changed its Soarian Clinicals CPOE several times after the initial configuration, from 2010 to 2016; however, the record does not reveal the ways in which the system changed.

On April 5, 2016, Dr. Alexandra Booth surgically removed Mr. Taylor's gallbladder. VHC had trained Dr. Booth on the Soarian Clinicals CPOE using the computer modules that VHC created. At the time of Mr. Taylor's treatment, Dr. Booth had been using Soarian Clinicals' CPOE regularly for several years.

Because Mr. Taylor was morbidly obese, and because Dr. Booth found he likely had sleep apnea, Dr. Booth determined that Mr. Taylor needed overnight monitoring with continuous pulse oximetry. Pulse oximetry is a small medical device that measures the amount of oxygen in the patient's blood, usually placed on a patient's finger.

Mr. Taylor's anesthesiologist, Dr. Jun, agreed that Mr. Taylor needed continuous pulse oximetry monitoring overnight. The "Anesthesia Postoperative Evaluation" signed by Dr. Jun on April 5, 2016 notes, "Admit to floor w/ continuous pulse oximetry. PACU staff notified." Dr. Jun's notation should have been conveyed to the nursing staff when Mr. Taylor was transferred from the surgical unit to the PACU (post-anesthesia care unit). Such communication is a patient safety requirement.

Dr. Booth entered thirty orders for Mr. Taylor into Soarian Clinicals' CPOE during the afternoon of April 5, 2016 while Mr. Taylor was recovering in the PACU. One order directed nursing staff to check Mr. Taylor's vital signs per VHC's guidelines, and three different orders related to Mr. Taylor's oxygen saturation.

The first read, "notify provider for oxygen saturation less than 92 percent." The second notified the nursing staff to keep Mr. Taylor on "oxygen via nasal cannula if necessary to maintain his oxygen saturation greater than 92 percent." Both orders were to start immediately. For the third order, pulse oximetry monitoring, Dr. Booth chose a continuous order and, in the ordering screen, chose the "daily" in the frequency field, "once" in the recurrence field, and "as ordered" in the conditional info field. She did not enter a start time for this order. When asked why she chose to enter the "once" in the recurrence field, Dr. Booth testified that out of all these options, none of them make any sense. "It's like the lesser of all the evils. None of those options make any sense." Unknown to Dr. Booth, VHC had programmed the recurrence "once" to default an order's start time to 10:00 am the following morning. Dr. Booth also did not know that VHC had programmed the system such that if she had instead not made any choices in the frequency or recurrence fields, the order would have defaulted to start immediately. Dr. Booth testified that she would have liked to have been trained about this default, but VHC did not provide her such training.

After making her choices, Dr. Booth clicked "Add to Order Session," which moved the pulse oximetry order from the ordering screen to the unsigned orders list. In the unsigned orders list, Dr. Booth's pulse oximetry order stated, "Pulse oximetry:

Continuous Once As Ordered; start on 4/6/2016 at 10:00." She read the pulse oximetry order in the unsigned orders list and thought the language "continuous once as ordered" was confusing, but she did nothing about it. She did not notice the start time for the pulse oximetry order was set to 10:00 a.m. the next morning. Dr. Booth electronically accepted all her orders for Mr. Taylor, and they went into effect.

At about 5:00 p.m. on April 5, 2016, a nurse viewed Dr. Booth's electronic orders, including the order that read: "Pulse Oximetry: Continuous Once As Ordered" with a start time of 10:00 a.m. on April 6, 2016. The nurse electronically acknowledged the pulse oximetry order and all other orders entered for Mr. Taylor. Continuous pulse oximetry was not initiated on Mr. Taylor. Mr. Taylor's vital signs were recorded at various points throughout the night of April 5 and into the morning of April 6. VHC guidelines required that patient vital signs be taken every four hours. The last entry in Mr. Taylor's medical records recording his vital signs was at 5:01 a.m. on April 6. When the nurses changed shifts at 7:00 a.m., the new nurse did not take vital signs or conduct a physical exam of Mr. Taylor because he was sleeping. There is no record of vital signs being taken again before Mr. Taylor coded around 10:30 a.m. on April 6, 2016. That morning, Dr. Booth came to Mr. Taylor's room in anticipation of his discharge. Dr. Booth found Mr. Taylor unresponsive and in

respiratory distress at approximately 10:30 a.m. Dr. Booth asked the day nurse about Mr. Taylor's pulse oximetry monitor, and the day nurse said, "I'm sorry."

In July 2016, VHC modified its CPOE to default orders for continuous pulse oximetry to "now." VHC made this change on its own without notifying Cerner HS or asking for assistance in modifying the configuration. When VHC's contract to use Soarian Clinicals expired in 2018, it considered staying with Cerner HS but ultimately switched to a new vendor, primarily due to cost concerns.

Cerner HS never received a complaint from VHC regarding the Soarian Clinicals CPOE. It never received a complaint from VHC regarding the incident with Mr. Taylor. It never received a complaint about the usability of its CPOE. It never received a complaint similar to the complaints raised by Plaintiff here. It never received a complaint that the CPOE allows the end users to populate order fields with contradicting recurrences and frequencies. And it never received a complaint that the CPOE allows customers to change the programmed default start time of "now" to different default start times of their choosing.

Cerner HS has never received a complaint that the ordering screen does not automatically refresh when a clinician chooses a recurrence with a programmed default start time other than "now." It never received a complaint that the CPOE does not "warn"

clinicians when they choose a recurrence with a programmed default start time other than "now." And it never received a complaint that the system should force clinicians to scroll to the bottom of the unsigned orders list before "signing" the orders.

Summary judgment is appropriate only when the "movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). To defeat a motion for summary judgment, a plaintiff cannot rely on mere allegations in his pleadings and must instead present admissible evidence that creates a material question of fact on the essential elements of his cause of action. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 252 (1986) ("The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff."); Glynn v. EDO Corp., 710 F.3d 209, 213 (4th Cir. 2013) ("[T]he non-moving party cannot solely rely on mere allegations or denials of [his] pleadings."). "Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no genuine issue for trial." Ricci v. DeStefano, 557 U.S. 557, 586 (2009). "Unsupported, self-serving allegations and denials are insufficient to create a genuine issue of material fact." Id.

When a U.S. district court exercises jurisdiction over state law claims pursuant to diversity of citizenship, the court must apply the law of the relevant state (in this case, Virginia) on all substantive matters, including the necessary elements of a tort action. See 18 U.S.C. § 1652. See also In re Lipitor, 892 F.3d 624, 646 (4th Cir. 2018) ("In a diversity case, state substantive law governs . . . the "substantive elements" of a tort action."). Under Virginia law, a plaintiff alleging negligent design in a products liability case "must prove that the product (1) contained a defect, which (2) rendered it unreasonably dangerous for ordinary or foreseeable use . . . (3) the defect existed when it left the defendant's hands, and that (4) the defect actually caused the plaintiff's injury." Putman v. Savage Arms, Inc., 2019 WL 1007527, at *2 (W.D. Va. Mar. 1, 2019) (quoting Alevromagiros v. Hechinger Co., 993 F.2d 417, 420 (4th Cir. 1993) (applying Virginia law)).

Plaintiff must do more than adduce evidence that the accident might have been avoided if the product had been designed differently. See Turner v. Manning, Maxwell & Moore, Inc., 217 S.E.2d 863, 868 (Va. 1975) (presenting evidence that the accident would not have occurred if the product had an additional feature was insufficient to impose liability). That a product does not incorporate the "best or most highly-advanced safety devices" does not render it "unreasonably dangerous for ordinary or

foreseeable use." Alevromagiros, 993 F.2d at 420. "The manufacturer is not an insurer and is not required to design and market an accident-proof product." Dorman v. State Indus., 787 S.E.2d 132, 139 (Va. 2016) (citing Turner, 217 S.E.2d at 868).

> Instead, manufacturers are required to design products that meet prevailing safety standards at the time the product is made. In determining whether a product's design meets those standards, a court should consider whether the product fails to satisfy (1) applicable government standards, (2) applicable industry standards, or (3) reasonable consumer expectations.

Id. (citing Sexton v. Bell Helmets, Inc., 926 F.2d 331, 336-37 (4th Cir. 1991)).

Here, Plaintiff's experts, Drs. Koppel and Elkin, offer exactly the type of opinions rejected by the Fourth Circuit in Alevromagiros. Both experts generically argue that Soarian Clinicals should have contained various design features that they believe would have made it "safer." But neither expert explains—and other evidence otherwise suggests—how Soarian Clinicals violated prevailing safety standards at the time of its manufacture.

There is only one government standard that applies to the design, security, and usability of EHR systems: The Health IT Certification Program promulgated by the ONC. Soarian Clinicals complied with the ONC standard, the only "prevailing safety standard" applicable to EHR systems at the time it was made. But neither Dr. Koppel nor Dr. Elkin mentions the ONC standard nor do

they discuss Soarian Clinicals' certification.

None of the features and functionality challenged in Plaintiff's claims are unusual. Rather, all are industry standard. Dr. Koppel instead promotes a different "industry standard" suggested by the National Institute of Standards and Technology. See Svetlana Z. Lowry, et al., Technical Evaluation, Testing, and Validation of the Usability of Electronic Health Records, NISTIR 7804 (Feb. 21, 2012). But Dr. Koppel admitted at his deposition that NISTIR 7804 was a proposal that ONC *rejected*. Dr. Koppel cannot without sufficient justification ignore the EHR testing standards that ONC adopted (45 C.F.R. § 170.314) in favor of a proposal that ONC rejected. See, e.g., Hines v. Wyeth, 2011 WL 2680842, at *6 (S.D. W. Va. July 8, 2011) (noting courts may exclude expert testimony as "too subjective and not expert in nature" when the expert fails to "identify an established, objective industry standard by which to judge the defendants' conduct"); Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 590 (1993) (stating an expert witness' "knowledge" under Fed. R. Evid. 702 "connotes more than a subjective belief or unsupported speculation"). Dr. Koppel's analysis cannot save Plaintiff's claims from summary judgment because he cites no accepted standard that Soarian Clinicals allegedly violated.

Dr. Elkin's report mentions usability guidelines published by HIMSS, but never explains how Soarian Clinicals failed to meet

those guidelines. Nor does Dr. Elkin attempt to explain how the HIMSS usability guidelines differ from ONC's federally regulated standard or why this Court should choose here to apply HIMSS instead of the ONC standard. Like Dr. Koppel, Dr. Elkin cannot ignore the only federal regulation in place and focus without explanation on a different source. See, e.g., Holmes v. Wing Enter, Inc., 2009 WL 1809985, at *7-8 (E.D. Va. June 23, 2009) (granting summary judgment where an expert failed to mention relevant industry standards and excluding expert for similar reasons); In re Rezulin Prods. Liab. Litig., 369 F. Supp. 2d 398, 425 (S.D.N.Y. 2005) (noting that selective reliance on information in the field is not a generally accepted method). Moreover, to the extent HIMSS *is* a relevant industry guideline, Cerner HS follows HIMSS guidelines in conducting its own safety and usability testing throughout the entire lifecycle of the Soarian Clinicals product.

Because Plaintiff's experts fail to identify or explain how Soarian Clinicals violated any applicable, accepted government or industry safety standard, Plaintiff can prevail only by convincing the jury that Soarian Clinicals' CPOE failed to meet reasonable consumer safety expectations. In Virginia, consumer expectations "may be proved from evidence of actual industry practices, knowledge at the time of other injuries, knowledge of dangers, the existence of published literature, and from direct evidence of what reasonable purchasers considered defective at the time."

Sexton v. Bell Helmets, Inc., 926 F.2d 331, 337 (4th Cir. 1991). An individual's "subjective expectations are insufficient to establish what degree of protection . . . society expects" from a product. Redman v. John D. Brush & Co., 111 F.3d 1174, 1181 (4th Cir. 1997). See also Sexton, 926 F.2d at 337 ("An examination of societal standards at any given point in time usually reveals an expectation that balances known risks and dangers against the feasibility and practicability of applying any given technology.").

None of Plaintiff's experts suggests that Soarian Clinicals violated consumer expectations, and the record evidence is directly contrary to such notion. The CPOE functionality at issue here is standard in the health technology field. Cerner HS received no customer complaints similar to those raised here, nor any notice of similar patient incidents. VHC never complained about its CPOE or even notified Cerner HS about the incident with Mr. Taylor. There is no evidence that Soarian Clinicals violated the expectations of VHC or any other customer. And Plaintiff's experts' subjective opinions as to what might be a "better" design are insufficient to establish consumers' objective, reasonable expectations. See, e.g., Evans v. Nacco Materials Handling Grp., 295 Va. 235, 248-49 (2018) (stating subjective expectations of one individual do not necessarily represent "the objective, reasonable expectations of consumers as a class"). On these

facts, Plaintiff cannot prove Cerner HS violated consumer expectations. Thus, Cerner HS is entitled to judgment.

Further, in order to prevail on any products liability claim, Plaintiff also must show the "unreasonably dangerous condition existed when the goods left the defendant's hands" and the product "was not substantially changed after the time of sale." Stokes v. Geismar, 815 F. Supp. 904, 907 (E.D. Va. 1993) (citing Logan v. Montgomery Ward & Co., 216 Va. 425, 428 (1975)). Plaintiff cannot meet this burden.

Of the claimed "defects," most were created through choices made by VHC. The software was delivered with removable drop-down menus, no content (e.g., blank drop-down menus), and a programmed default start time of "now" for all orders. After delivery, VHC chose how many drop-down menus to use; VHC chose the selections available in the drop-down menus; VHC chose to default the start time to 10:00 a.m. the next morning for the recurrence "once"; and, notably, VHC could have programmed the system to issue a warning when the recurrence "once" was chosen. None of these alleged "defects" existed when the product left Siemens' hands. In addition, the evidence shows that VHC could have originally configured the system the way that Plaintiff now claims it should have been configured. After the incident with Mr. Taylor, in fact, VHC modified the system such that continuous pulse oximetry orders defaulted to "now." VHC made that change on its own

accord, without assistance from Cerner HS.

The evidence is also clear that VHC changed the CPOE multiple times, in unknown ways, after 2010 and before the incident with Plaintiff. That is, even if the alleged "defects" were present when Siemens delivered the system, VHC admits it substantially changed the product after its delivery. Cerner HS is entitled to summary judgment on these facts. See, e.g., Lemons v. Ryder Truck Rental, Inc., 906 F. Supp. 328, 333-34 (W.D. Va. 1995) (granting summary judgment because Plaintiff failed to demonstrate product was in same condition as it was when it left the defendant's control). See also Wilder v. Toyota Motor Sales, U.S.A., Inc., 23 F. App'x 155, 158 (4th Cir. 2001) ("By failing to offer any credible evidence of a defect in the airbag system that occurred while the truck was in [Defendant's] hands . . . [Plaintiff] failed to meet the burden Virginia law imposes on him.").

As Plaintiff is unable to prove that the CPOE was unreasonably dangerous and unable to prove that each of the alleged defects existed when the product left Cerner HS' hands, summary judgment on Plaintiff's negligent design claim is warranted.

With regard to Plaintiff's failure to warn allegations, it is unclear if Plaintiff claims (i) that the Soarian Clinicals software failed to warn Dr. Booth when she selected an order

recurrence VHC chose to default to a specific start time, or (ii) that Cerner HS failed to warn VHC about the system's alleged dangers. The former allegation is one of negligent design and fails for the reasons set out previously. If Plaintiff is claiming the latter, the claim still fails.

To establish a viable claim for failure to warn, a plaintiff must prove that the manufacturer (1) knew or had reason to know that the product was likely to be dangerous for its intended use, (2) had no reason to believe the intended user would realize its dangerous condition, and (3) failed to exercise reasonable care to inform the user of its dangerous condition or facts which made it likely to be dangerous. See, e.g., Funkhouser v. Ford Motor Co., 285 Va. 272, 281 (2013). To show the manufacturer had notice under the first prong, a plaintiff may present evidence of similar incidents only if he establishes "(1) that the defect is the same or similar to that alleged to have caused the injury of which that party complains, and (2) that the circumstances in the earlier incidents are 'substantially similar' to the one at bar." Musick v. Dorel Juv. Grp., 2011 WL 5110404, at *1 (W.D. Va. Oct. 22, 2011) (citing Gen. Motors Corp. v. Lupica, 237 Va. 516, 379 (1989)). See also Funkhouser, 285 Va. at 281 (excluding evidence of other alleged incidents because plaintiff could not establish that they occurred "under substantially the same circumstances").

Plaintiff has failed to produce evidence Cerner HS had any knowledge sufficient to trigger a duty to warn. Plaintiff has provided no evidence that Cerner HS knew or had a reason to know that its CPOE was likely to be dangerous for its intended use or that VHC, a sophisticated billion-dollar hospital, would not have been capable of realizing any purported dangerous conditions at the time it received Soarian Clinicals.

Cerner HS is not aware of any other patient incident occurring under circumstances like the Plaintiff's. Plaintiff's expert Dr. Koppel sought to rebut this fact by referencing three reports against Soarian Clinicals found in the Food and Drug Administration's MAUDE database. MAUDE collects clinicians' reports of adverse events involving medical devices. Dr. Koppel attempts to use these reports to demonstrate Cerner HS knew its software could pose risks to patients. He admitted, however, he does not know how the healthcare organizations associated with these reports configured their systems. Without this information, Dr. Koppel could not effectively compare these systems to VHC's and accordingly cannot show the circumstances of each incident were substantially similar to the present matter.

Dr. Koppel also cites a single request for assistance from a Siemens' customer who entered a ticket requesting that the field containing the start time be changed from its standard grey font color to red or yellow. The customer reported no patient harm,

and in no way does the ticket demonstrate that the system was "dangerous" and could lead to injury. Given the lack of substantial similarity, the inferences Dr. Koppel draws from the data he cites are "speculation" and "guess work" and cannot save Plaintiff's claim from summary judgment. E.g., Oglesby v. Gen. Motors Corp., 190 F.3d 244, 250 (4th Cir. 1999) ("A reliable expert opinion must be based on scientific, technical, or other specialized *knowledge* and not on belief or speculation, and inferences must be derived using scientific or other valid methods.") (emphasis in original); Goodrich v. John Crane Inc., 2018 WL 4677773, at *14-16 (E.D. Va. Sept. 28, 2018) (deducing that an expert's claim "appears to be little more than speculation and guesswork").

Perhaps even more fundamentally, even if Plaintiff could prove that Defendant had a duty to warn of the alleged danger associated with Soarian Clinicals' CPOE, Plaintiff cannot prove that Cerner HS had reason to believe that VHC would not itself realize the purported danger. See Funkhouser, 285 Va. at 281, 736 S.E.2d at 313. The "defects" about which Plaintiff complains were either (a) entirely the result of VHC's configuration choices, (b) well known to VHC after six years of use, or (c) both. VHC chose the number of drop-down menus to use in its CPOE ordering screen, and it could remove or add options as it saw fit. VHC chose the content within the drop-down menus and chose to default

the recurrence "once" to begin at 10:00 a.m. the next morning, matching its practice to that of its prior EHR system. VHC could have programmed the system to display a warning when the "once" or any other order type was selected.

Any other alleged "defects" with the way the CPOE functioned would have been well known to VHC after six years of use. Yet VHC never logged a complaint with Siemens or Cerner HS regarding any issue related to its CPOE. VHC never notified Cerner HS about the incident with Mr. Taylor, much less complained that the CPOE was "defective" and caused patient harm—not even after Plaintiff sued VHC. VHC did not believe Soarian Clinicals contained a dangerous condition.

To prevail on either his negligent design or his failure-to-warn theory, "the plaintiff must demonstrate with *reasonable certainty* that the defendant caused the plaintiff's injuries." Stokes v. Geismar, 815 F. Supp. 904, 907 (E.D. Va. 1993) (internal citations omitted) (emphasis added). "Plaintiff must also demonstrate with 'reasonable certainty' that if there is more than one possible cause of the accident, Defendants caused the injury." Sprouse v. Am. Tire Distrib., Inc., 2009 WL 1404735, at *3 (E.D. Va. May 15, 2009). See Stokes, 815 F. Supp. at 908 (requiring the plaintiff to show with "reasonable certainty" that the defendant caused the injury). When an injury has more than one possible cause, the plaintiff's experts are

required to "take serious account of other potential causes, or offer an explanation for why the proffered alternative cause[s] w[ere] not the sole cause of the problem." Waytec Elec. Corp. v. Rohm & Haas Elec. Materials, 255 F. App'x 754, 759 (4th Cir. 2007) (internal citations omitted).

The parties do not dispute that Mr. Taylor suffered harm because he did not receive overnight pulse oximetry monitoring. But they do dispute *who* is responsible for the pulse oximetry monitor not being placed on Mr. Taylor's finger. Even a cursory review of the record suggests multiple possible causes of Mr. Taylor's harm. Plaintiff's actions further demonstrate he recognizes this, as he has already sued (and settled with) VHC, as well as Dr. Booth's and the nursing staff's employers.

But Plaintiff's experts in this case failed to take serious account of, or to rule out, VHC, Dr. Booth, or the nursing staff as potential causes of Mr. Taylor's harm. Dr. Koppel conceded that he was not asked to "opine on whether Dr. Booth's actions were a cause of Mr. Taylor's harm." Dr. Elkin testified that he did "not have enough information" to answer whether Dr. Booth made errors in caring for Plaintiff. The inexplicable failure to present evidence ruling out other potential causes is fatal to Plaintiff's liability claims. See, e.g., Sprouse, 2009 WL 1404735, at *4 (requiring Plaintiff's evidence either tend "to eliminate all reasonable possibilities that some other party or

cause is to blame for the accident" or the only cause would be the existence of a defect); Hartwell v. Danek Med. Inc., 47 F. Supp. 2d 703, 709, 716 (W.D. Va. 1999) (citing Boyle v. United Tech. Corp., 792 F.2d 413, 416 (4th Cir. 1986)) (presenting evidence that either the defendant or a third party could have caused the accident entitled defendant-manufacturer to summary judgment). Plaintiff's inability to prove causation requires the dismissal of all claims.

The Supreme Court of Virginia has a "clearly-expressed view that [negligence-based] products liability actions may take one of three forms." Torkie-Tork v. Wyeth, 757 F. Supp. 2d 567, 571-72 (E.D. Va. 2010) (citing Morgen Indus. v. Vaughan, 252 Va. 60, 65 (1996)). See Powell v. Diehl Woodworking Mach., Inc., 198 F. Supp. 3d 628, 633 (E.D. Va. 2016) ("Virginia law only recognizes three products liability claims: negligent assembly or manufacture, negligent design, and failure to warn."). Courts have made clear that there is no "theory of general negligence in products liability." Sutherlin v. Lowe's Home Ctrs., LLC, 2014 WL 7345893, at *8 (E.D. Va. Dec. 23, 2014) (refusing to analyze a general negligence count on summary judgment in product liability case). Given this (and because Plaintiff's claims are duplicative in nature), the Court also finds summary judgment proper on Count II of Plaintiff's Complaint.

For the foregoing reasons, Defendant Cerner HS is entitled

to summary judgment on all claims. An accompanying order shall issue.

Claude M. Hilton
CLAUDE M. HILTON
UNITED STATES DISTRICT JUDGE

Alexandria, Virginia
November 20, 2020